



International Conference on Harmonization
of Technical Requirements for Registration
of Veterinary Medicinal Products

THIRD CONFERENCE ON INTERNATIONAL HARMONISATION OF VETERINARY MEDICINAL PRODUCTS

May 25 – 27, 2005

Washington, DC • USA

The International Cooperation on Harmonisation of Technical Requirements for the Registration of Veterinary Medicinal Products (VICH) is a unique project that brings together the regulatory authorities of the United States, Japan and the European Union and experts from the animal health industry in the three regions to discuss scientific and technical aspects of new product registration. Regulatory authorities and industry experts from Canada, Australia and New Zealand participate in an observer capacity.

This is the third International VICH Conference and marks the closure of the first phase of the harmonisation of regulatory requirements among the VICH regions. This public conference will discuss the results of the various VICH Expert Working Groups and enable the public to provide comments on the on-going activities. The conference will also unveil the second phase of the VICH process.

THIS CONFERENCE IS CO-SPONSORED BY

MEMBERS

- The European Commission and the European Agency for the Evaluation of Veterinary Medicinal Products (EMA) – European Union (EU)
- The Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF) – Japan
- The Food and Drug Administration Center for Veterinary Medicine (FDA/CVM) and the Department of Agriculture Center for Veterinary Biologicals (USDA/CVB) – United States
- The International Federation for Animal Health – European Union (IFAH-EU)
- The Japanese Veterinary Products Association (JVPA)
- The Animal Health Institute (AHI)

ASSOCIATE MEMBER

- The International Epizootics (OIE)

OBSERVERS

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) – New Zealand Food Safety Authority (NZFSA)
- The National Association for Crop Production and Animal Health (AVCARE/Australia) and the Agricultural Chemicals and Animal Remedies Manufacturers' Association of New Zealand (AGCARM/New Zealand)
- Health Canada (HC) – Veterinary Drugs Directorate (VDD) and Canadian Food Inspection Agency (CFIA) – Veterinary Biologics Section (VBS)
- The Canadian Animal Health Institute (CAHI)

INTERESTED PARTIES

- Association of Veterinary Biologics Companies (AVBC)
- CAMEVET (representing authorities and industry associations from Latin American countries)

VICH SECRETARIAT

- The International Federation for Animal Health (IFAH)

WEDNESDAY, MAY 25, 2005
.....**4:00 PM – 7:00 PM****Registration Open****6:00 PM****Welcome Reception**
.....**THURSDAY, MAY 26, 2005****7:30 AM – 4:00 PM****Registration Open****8:30 AM****Plenary Session I:
Official Opening Session***Chair: Richard Hill (USDA/APHIS)***Introductory Remarks***Lester Crawford, Acting Commissioner,
US Food and Drug Administration***9:15 AM****VICH: The history, process
and accomplishments***Herve Marion, VICH Secretariat***9:30 AM****Keynote Address – Global Trends:
An Industry Perspective***Pedro Lichtinger, IFAH Board Member
and President Pfizer Animal Health***10:00 AM****Coffee break****10:30 AM****Focus Session A****Expert Working Group on Ecotoxicity
Environmental Impact Assessment***Chair: Michael McGowan (AHI)**Presenters: Joseph Robinson (AHI)**Joop DeKnecht (EU)***12:00 NOON****Lunch****1:30 PM****Focus Session B****Expert Working Group on Safety***Chair: Kornelia Grein (EMA)**Presenters: Thomas Mulligan (FDA/CVM)**Haydee Fernandez (FDA/CVM)**Mark Hurtt (AHI)**John Reeve (NZFSA)***3:00 PM****Coffee break****3:30 PM****Focus Session C****Expert Working Group on Quality***Chair: Yoshiyuki Takahashi (JMAFF)**Presenters: Kouko Hamamoto (JMAFF)**Arthur Faulkner (AHI)**Dennis Bensley (FDA/CVM)**Norbert Möller (EU/BVL)***5:00 PM****Adjourn for day****6:00 PM****Gala dinner at Mount Vernon Estate***Meet in the hotel lobby – 11th Street**Exit – transportation to be provided.*

FRIDAY, MAY 27, 2005

.....

7:30 AM – 4:00 PM

Registration

8:00 AM

Focus Session D

Expert Working Group on Biologicals Quality Monitoring

Chair: Sachio Tokiyoshi (JVPA)
Presenters: Shigeyuki Nakamura (JMAFF)
Larry Elsken (USDA)
Hans Draayer (AHI)

Expert Working Group on Pharmacovigilance

Chair: Ian Alexander (VDD/Health Canada)
Presenters: Lynn Post (FDA/CVM)
David Hustead (AHI)
Declan O'Rourke (IFAH-EU)
Cornelia Ibrahim (EU)

10:00 AM

Coffee Break

10:30 AM

Focus Session E

Expert Working Group on Target Animal Safety

Chair: Peter Holdsworth (AVCARE)
Presenters: Tadashi Nagata (JVPA)
Manfred Moos (EU)
Donna Gatewood (USDA)

Expert Working Group on Antimicrobial Resistance

Chair: Anne Gautrais (EC)
Presenters: Jordi Torren (EMEA)
Robin Bywater (IFAH-EU)
William Flynn (FDA/CVM)

12:30 PM

Lunch

2:00 PM

Plenary Session II:

Benefits of the VICH Initiative

Panel discussion with representatives from the regulatory agencies and industry from the participating regions and observers nations

Chair: Robert Livingston (AHI)
Presenters: Debbie Morris (NZFSA)
Susanne Zänker (IFAH-EU)
Panelists: Jean Szkotnicki (CAHI)
Anne Gautrais (EU)
Sachio Tokiyoshi (JVPA)

3:00 PM

Coffee Break

3:30 PM

Plenary Session III:

VICH – The Vision for the Future

Chair: Richard Hill (USDA)

The Future of ICH

Speaker to be announced

Canadian Smart Regulation Initiative

Julia Hill, Executive Director, Privy Counsel Office

VICH Phase II

Patrick Dehaumont (OIE)

4:45 PM

Conclusion of Conference

*Stephen Sundlof, Director, FDA Center
for Veterinary Medicine*

5:00 PM

Closure of the Conference

CONFERENCE INFORMATION

The Conference Organization is provided by



Conference Location

Grand Hyatt Washington
1000 H Street, NW
Washington, DC 20001 USA
Tel: +1.202.582.1234 Fax: +1.202.637.4781

Registration Desk

Registration and distribution of conference materials will take place at the desk located on the Constitution Level (3B) during the following hours:

| | |
|--------------------------|--------------------------|
| Wednesday, May 25 | 4:00 PM – 7:00 PM |
| Thursday, May 26 | 7:30 AM – 4:00 PM |
| Friday, May 27 | 7:30 AM – 4:00 PM |

Language

All presentations will be given in English. Translations to Japanese will be available.

Meals, coffee breaks

The registration fee for the conference includes:

Lunches

Thursday, May 26 and Friday, May 27, a buffet lunch will be served in a room located on the Constitution Level of the conference hotel.

Coffee Breaks

Thursday, May 26 and Friday, May 27, morning and afternoon coffee will be served on the Constitution Level of the conference hotel near the meeting room.

Travel Documentation

Please note that you must have a machine-readable passport (MRP) to enter the US, even if you are traveling from the 27 Visa waived countries OR you must have Visa. This is a relatively new rule that went into effect in October of last year. We want your visit to our country to be enjoyable, so please make sure that your travel documentation is current with the latest requirements.

Weather

The weather in Washington at this time of year should be pleasant with daytime highs of 76° F / 25° C and evening lows of 56° F / 14° C.

Transportation

Washington, DC is serviced by three airports. Parking in Washington is limited and expensive; we recommend that you take a cab or shuttle from the airports to the hotel.

Dulles International Airport

approximately 28 miles from the hotel
(\$45 cab each way)

Reagan Washington National Airport

approximately 5 miles from the hotel
(\$14 cab each way)

Baltimore-Washington International Airport

approximately 40 miles from the hotel
(\$60 cab each way)

SOCIAL EVENTS

Welcome Reception

Wednesday, 25 May the conference will begin with an evening reception at the Washington Grand Hyatt Hotel. Take this opportunity to meet the other participants in the conference, as well as members of the VICH Steering Committee and Expert Working Groups.

Gala Dinner

Thursday, 26 May we will travel to Mount Vernon Estate, the home of our first president, George Washington. Mount Vernon is located on the Potomac River approximately 16 miles south of Washington. Participants will tour the mansion and partake of a colonial dinner. Transportation will be provided.

Tipping

Tipping is voluntary; gratuities are not automatically added to the bill. Here are a few tipping guidelines: Servers are usually given 15% of the bill. For outstanding service, tip 20%. Taxi drivers usually receive 15% of the fare, and doormen, skycaps and porters are usually tipped \$1 per bag.

Electricity

The electricity used in Washington, DC is 110 volts. European appliances will require a voltage transformer and adaptor.

BADGES MUST BE WORN FOR ALL CONFERENCE ACTIVITIES AND SOCIAL EVENTS

REGISTRATION FEES

Government – \$200 US

Industry (members of IFAH, AHI, IFAH-EU, JVPA, CAHI, AVCARE, AGCARM, AVBC, CAMEVET) – \$500 US

Others – \$750 US